UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

In Re: COOK MEDICAL, INC., IVC FILTERS MARKETING, SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	)	1:14-ml-02570-RLY-TAB MDL No. 2570
This Document Relates to:	)	
Tonya Brand, 1:14-cv-06018-RLY-TAB	)	

ENTRY ON THE COOK DEFENDANTS' MOTION TO EXCLUDE TESTIMONY OF JAMES CARLSON, Ph.D.

Plaintiff has designated former Cook employee Dr. James Carlson as a non-retained expert witness. He was employed by Cook from 2004-2014 as a senior engineer and metallurgist.[1] (Filing No. 9140-1, Deposition of Dr. James Carlson at 27, 33). He was responsible for assisting William Cook Europe with any production-related problems, such as warranty returns on IVC filters. (*Id.* at 49). He performed a metallurgical failure analysis to determine why, for example, the filter fractured. (Carlson Dep. at 49, 59). In fact, on his CV, he notes that he is an expert in fracture analysis. (*Id.* at 31).

[1] Dr. Carlson defined a metallurgist as "an engineer that has dedicated his career [and] education to the understanding of metallic elements and/or alloys." (*Id.* at 24). Metallurgy "encompasses everything from the melting of the material all the way to its finished form." (*Id.*). It is a "very broad field" which "includes [] chemistry, physics, mechanical behavior, [and] thermodynamics." (*Id.* at 25).

In his deposition, Dr. Carlson testified that tilt, perforation (or wall penetration), and fracture are related. (*Id.* at 79 ("Yes. I think all three are related, the tilt and the wall penetration and the fracture."). This is because, he explained, tilt places filters under stress; tilt can lead to perforation; perforation increases stress on filters; perforation can lead to fracture. (*Id*. at 79-80, 108). Cook objects to this testimony on four grounds. First, Cook argues Dr. Carlson should have provided an expert report under Rule 26(a)(2)(B) because his opinions on the relationship between tilt, perforation, and fracture exceed his personal knowledge and ground-level involvement as a former Cook employee and metallurgist. Second, Cook argues Dr. Carlson is not qualified to testify or offer opinions on the relationship between tilt, perforation, and fracture. Third, Cook argues his testimony and opinions on the relationship between tilt, perforation, and fracture are unreliable. Lastly, Cook argues his opinions are irrelevant to *Brand* and unfairly prejudicial.

I. Discussion

"[A] former employee may be a non-retained expert for the purposes of Rule 26(a)(2) if he is a percipient witness and is testifying based upon his personal knowledge of the facts or data at issue in the litigation." *Guarantee Tr. Life Ins. Co. v. Am. Med. & Life Ins. Co.*, 291 F.R.D. 234, 237 (N.D. Ill. 2013); *see also Indianapolis Airport Auth. v. Travelers Property Casualty Co. of Am.*, 849 F.3d 355, 371 (7th Cir. 2017) (finding witness was not required to file Rule 26(a)(2)(B) expert report where his testimony stemmed not from his role as an expert but from his "ground-level involvement in the events giving rise to the litigation") (quoting *Downey v. Bob's Discount Furniture*

Holdings, Inc., 633 F.3d 1, 6 (1st Cir. 2011)). If he testifies beyond the scope of his observation, however, he is treated as a retained expert and must provide a written report pursuant to Rule 26(a)(2)(B). *Martin v. Stoops Buick*, 1:14-cv-00298-RLY-DKL, 2016 WL 4088132, at *1 (S.D. Ind. 2016).

Over Cook's objection, the court finds Dr. Carlson was not required to submit an expert report because his testimony is based on his observations and opinions he formed during his metallurgical evaluations of Celect filter fractures. (*See* Carlson Dep. at 79-80 ("[S]o once it's tilted, you know, it puts a lot of stress on the bent leg and plus it puts the filter in a kind of an up – a strangely loaded condition so there's more potential for a leg to kind of puncture through, like a needle, through the wall of the IVC" and the perforation influences whether there is a fracture); *see also id.* at 108 ("Q: So, when a filter tilts, perforates and fractures, it's the tilting and perforation that causes the fracture, right? A: Yes. It puts the – either the primary or secondary leg in an unusually high stress situation.")). Dr. Carlson is not opining on the *cause* or the *rates* of those adverse events. (*Id.* at 82 (testifying he was not opining on the "root cause of the problem"); *see also id.* at 108 (testifying he did not know how often Cook filters tilt and perforate)). He is simply opining on the *relationship* between the three. (*Id.* at 79). Furthermore, as a former senior metallurgical engineer for Cook, he is qualified to testify and opine on the same.

Next, Cook argues Dr. Carlson failed to "use[] any methodology at all in arriving at the views he states." The court finds otherwise. Cook's policy required a fracture analysis every time a filter was returned due to fracture. (*Id.* at 53). As noted above, Dr.

Carlson was one of only two Cook employees who performed a failure analysis of fractured Celect filters. (*Id.* at 59 (testifying either him or Brian Choules performed metals analysis of fractured filters)). To begin, he would review the complaint report which provided information related to the filter fracture—when the filter was placed, what cavagrams showed in terms of tilt, perforation, or fracture, and when those adverse events were understood to have occurred—and other supporting documentation. (*Id.* at 66-69). Dr. Carlson provided "technical expertise" in analyzing the complaint. (*Id.* at 70). He would "look[] at the area of fracture" to determine whether "there was a manufacturing defect in the wire from how it was manufactured from Fort Wayne Metals or . . . any manufacturing defect associated with the forming of the secondary wire over in Denmark" or any other "atypical" explanation for the fracture. (*Id.* at 73). In the absence of a manufacturing defect or atypical fracture, he would evaluate whether the "fracture location was typical for an area of high stress." (*Id.*). If so, he concluded that the fracture was caused by "too much stress on the metal." (*Id.* at 77). In so doing, he observed that there is a relationship between tilt, perforation, and fracture. (*Id.* at 79). The methodology Dr. Carlson employed to determine the likely cause of Celect filter fractures in his role as senior metallurgist at Cook is reliable. The conclusion he drew regarding the relationship between tilt, perforation, and fracture, which he gleaned as part of his failure analysis, is also reliable.

In addition, Cook argues Dr. Carlson's testimony should be excluded because he did not examine or evaluate Plaintiff's filter. While that is true, he did analyze other Celect filters which tilted, perforated the IVC, and fractured—the same set of

circumstances that befell Plaintiff's Celect filter. The risk of and relationship between tilt, perforation, and fracture are therefore relevant to show the Celect had a design defect.

Lastly, Cook argues Dr. Carlson's testimony is unfairly prejudicial because he evaluated fractured filters involving patients less than a handful of times. The point of Dr. Carlson's testimony is to establish the relationship between tilt, perforation, and fracture. Cook may not like his testimony, but it is not unfair. At trial, Cook may cross-examine Dr. Carlson and elicit the following testimony: that filter fracture was rare, that tilt does not always lead to perforation, and perforation does not always lead to fracture. (*Id.* at 437) ("I meant that in the very few fracture cases that I looked at over my ten-year career, which was actually less than ten, we observed a set of identical-identifiable characteristics in the fracture process, such as tilt, perforation and fracture. They didn't always occur."); *id.* at 438 ("Q: So does tilt, in – in your experience, always lead to perforation? A: No.); *id.* at 439 ("Q: In your experience, does perforation always lead to fracture? A: No, it doesn't.")). Once the jurors hear all of Dr. Carlson's testimony, they will understand the extent of his opinion: that there is a relationship between tilt, perforation, and fracture, but that tilt does not always lead to perforation, and perforation does not always lead to fracture.

II. Conclusion

The court finds Dr. Carlson is qualified to offer opinions in this case based on his personal knowledge and experience as senior metallurgical engineer at Cook. The court further finds his opinions are relevant, reliable, and helpful to the jury. Therefore, Cooks'

Motion to Exclude Expert Opinions of James Carlson, Ph.D. (Filing No. 8617) is **DENIED**.

SO ORDERED this 9th day of November 2018.

RICHARD L. YOUNG, JUDGE
United States District Court
Southern District of Indiana

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